

Appl. No. : 10/009,916  
Filed : August 13, 2002

### REMARKS

The Specification has been amended to correct minor informalities. The paragraph on page 59 incorrectly identified the plasmid containing the SodC gene in pCRw.1TOPO as pALK14. As the pALK14 has been deposited with the ATCC, those skilled in the art should be able to reproduce the sequence of pALK14 and to recognize that this statement is an error. Thus, no new matter has been added herewith. In addition, the designation of the primer on page 58, line 30 as RA175 was a typographical error and should read "RA147".

The changes made to the Specification by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined. No new matter has been added herewith.

### Response to Restriction Requirement

This is in response to the Restriction Requirement mailed from the United States Patent and Trademark Office on May 17, 2004. Therein the Examiner indicated that the above-captioned application contains seven inventions defined as follows:

Group I (Claims 1-4, 6-8, 10-11, 13-14, 17-20, 21-23, 25-26, and 49 drawn to an isolated or recombinant immunogenic polypeptide comprising the Lawsonia SodC polypeptide, variant or truncated variant thereof, a vaccine composition comprising SEQ ID NO:1 or the amino acid sequence encoded by pALK14.

Group II (Claims 28-30, 37-42, 46 and 47, drawn to a vaccine vector, polynucleotides that encodes the immunogenic polypeptide SEQ ID NO:1 or polynucleotides SEQ ID NO:2 or Plasmid pALK14 or plasmid pALK13.

Group III (Claims 31-33) drawn to an antibody that binds to SEQ ID NO:1 or the amino acid sequence encoded by pALK14.

Group IV (Claims 27 and 48) drawn to a combination vaccine composition comprising the first component comprising SEQ ID NO:1 or the amino acid sequence encoded by pALK14 and a second immunogenic component comprising OmpH, FigE, hemolysin and autolysin.

Group V (Claims 34-35) drawn to a method for diagnosing Lawsonia intracellularis using an antibody that binds to SEQ ID NO:1 or the amino acid sequence encoded by pALK14.

Group VI (Claim 36) drawn to a method of identifying a previous or current infection of Lawsonia intracellularis using an immunogenic polypeptide, SEQ ID NO:1, or the amino acid sequence encoded by pALK14.

Group VII (Claims 43-45) drawn to a method for identifying Lawsonia intracellularis in a sample using a polynucleotide that encodes the immunogenic polypeptide SEQ ID NO:1 or polynucleotide SEQ ID NO:2 or Plasmid pALK14 or Plasmid pALK13.

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In response to this requirement, Applicants elect to prosecute Group I, Claims 1-4, 6-8, 10-11, 13-14, 17-20, 21-23, 25-26, and 49. In addition, the Examiner has required a further election of one of the following inventions: Polypeptide comprising SEQ ID NO:1, The amino acid sequence encoded by the nucleotide sequence pALK14; Plasmid pALK14; Plasmid pALK13; and Nucleic acid SEQ ID NO:2. Applicants provisionally elect a polypeptide comprising SEQ ID NO:1. The elections are made with traverse.

#### **Traverse of the Restriction Requirement**

In addition, because of the arguments presented below, the invention defined by all of the claims on file constitute a special technical feature under PCT Rule 13.1.

In the Restriction requirement, the Examiner believes that restriction of the subject matter under examination in the instant application is required under 35 U.S.C. 121 and 372, on the basis that the application as filed defines several different inventions which are not so linked as to define a single general inventive concept under PCT Rule 13.1.

The Examiner states that the invention identified in Groups I-VII above *supra* do not relate to a single general inventive concept under PCT Rule 13.1, because the invention of each group has different modes of operation functions, and effects not capable of being used together.

Applicant respectfully traverses the Examiner's allegation that the instant application defines seven different invention. The expression "special technical feature" is defined in PCT Rule 13.2 to mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The subject matter of each of claims 1-4, 6-8, 10-11, 13-14, 17-20, 21-23, and 25-49 now pending in the application incorporates the special technical feature of SodC polypeptides or their encoding nucleotide sequences. Groups I-VII are merely different aspects of a single invention. Specifically, the polynucleotide of Group II encode the SodC polypeptide or variant thereof of Group I, the antibodies of Group III are specifically raised against the SodC polypeptide or variant thereof of Group I, the methods of Groups V-VII employ the SodC polypeptides, polynucleotides or antibodies of Groups I, II and III respectively, and the combination vaccine of Group IV also requires the presence of a SodC polypeptide. Clearly, the embodiments of Groups I-VII all relate to the SodC polypeptides or their encoding nucleotides sequences.

The Examiner has required the further election of one of the following inventions:

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Polypeptide comprising SEQ ID NO:1;  
The amino acid sequence encoded by the nucleotide sequence pALK14;  
Plasmid pALK14;  
Plasmid pALK13; and  
Nucleic acid SEQ ID NO:2.

The Examiner contends that this further restriction is required because the identified molecules do not share any common structure or function. In addition, the Examiner has required clarification of the relationships among these molecules.

Based on the specification and the Sequence Listing, it is clear that the polynucleotide sequence of SEQ Id NO:2 encodes the amino acid sequence of SEQ ID NO:1. Additionally, based on information provided from Dr. Robert Ankenbauer (a co-inventor), the plasmid pALK14 encodes the full-length SodC protein as set forth in SEQ Id NO:1 and does not contain, in the relevant portion, any heterologous protein sequence. pALK13 is an OmpH-encoding plasmid as described in WO 00/69905, also filed by the present Applicants.

#### Conclusion

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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